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Apparatus for monitoring a patient

The invention relates to an apparatus for monitoring the condition of a patient and to a monitoring method.

It is known that monitoring of certain parameters, for example, blood gases - in particular oxygen partial pressure (pO_2), carbon dioxide partial pressure (pCO_2) and pH - in bodily fluids can give useful information regarding the condition of a patient. In practice, such monitoring is carried out in many cases by taking samples from the patient at intervals and analysing each sample. Also known are so-called "continuous" monitoring devices, for example the device commercially available under the trade mark PARATREND, which have an elongate sensor portion which can be introduced into a blood vessel through a previously introduced catheter. The concentration of oxygen and carbon dioxide and the pH is monitored by optical sensing means housed in the sensor portion. Those devices enable the parameters to be monitored substantially continuously, so that attendant medical staff will become aware, without the delays inherent in sampling and sample analysis, of any significant change in patient condition. "Substantially continuously" as used herein is to be understood to include monitoring non-continuously at relatively high frequency, for example, at intervals of no more than five minutes, for example, not more than one minute,

especially intervals of not more than one second. Continuous monitoring devices may, with suitable modification, be inserted into soft tissue or introduced into organs for determining analytes in the tissue or organ in question.

The continuous monitoring devices may require calibration before use. After insertion into the patient, re-calibration is not feasible, and the monitoring device may be susceptible to drift away from the calibration values. Whilst any such drift tends to be small, it is not unusual for the monitoring device to remain in the patient for a number of days so that, cumulatively, the drift may become material with the result that data measured a number of days after introduction of the device cannot reliably be compared with data measured shortly after its introduction.

The present invention provides an apparatus for monitoring a patient, comprising an invasive optical sensor device for monitoring substantially continuously a parameter relating to a bodily fluid of the patient and an analyser device in communication with the sensor device for analysing a sample of bodily fluid withdrawn from the patient to derive information relating to the sample of bodily fluid.

References below to "sensor device" are to be understood as referring to a sensor device for monitoring substantially continuously a parameter

relating to a bodily fluid of the patient. The word 'invasive' is to be understood as meaning that at least a part of the sensor device is, in use, inserted into the body of the patient and is in contact with the bodily fluid. The sensor device will normally include a sensor probe for insertion into the patient, interrogation means for interrogating the sensor probe and data collection means for collecting data from the sensor probe. The interrogation means and/or the data collection means may be remote from the sensor probe, for example, in an interface unit or in a monitor upon which data can be displayed, or may be incorporated into the sensor probe structure. The interrogation means and data collection means will be in communication with the sensor probe by any suitable means.

The apparatus of the invention enables both substantially continuous monitoring of a parameter by the sensor device and intermittent ex vivo or in vitro analysis of samples of bodily fluid by the analyser device to be carried out, providing information from both sources for use by a clinician.

The information relating to the sample of body fluid is advantageously the parameter monitored by the sensor device. Advantageously, the apparatus is so arranged that information derived by the analyser device can be compared with measurements made by the sensor device. The data from the sensor device and the analyser device

may be supplied to a common display device, at which each set of data is displayed and can be compared visually. If desired, the data from the sensor device and the analyser device may be supplied to a common processing means in which the comparison of the data is effected.

Whereas, in practice, measurements can be made by the sensor device essentially in real-time, measurements relating to a sample withdrawn from the patient will normally be available only after a delay, typically after the sample has been sent to a laboratory for analysis.

Advantageously, the measurements made by the sensor device are recorded and information derived by the analyser device relating to a sample of bodily fluid can be compared with a measurement made by the sensor device substantially contemporaneously with the withdrawal of that sample. This enables a more reliable comparison to be made between the two sets of data, which may be particularly important where the parameter is changing at a material rate, for example because of a deterioration in the patient's condition.

Advantageously, the apparatus is such that comparison of the data from the analyser device with data from the sensor device can be used for calibration and/or re-calibration of the sensor device. Whilst in principle, a first calibration of the sensor device may

be carried out based on comparison of readings from the sensor device, in situ in the patient, with readings from the analyser device, it may in practice be preferable for an initial calibration of the sensor device to be carried out before insertion of the sensor device into the patient, subsequent re-calibrations then being based on a comparison of readings from the sensor device in situ in the patient with readings from the analyser device.

Advantageously, the apparatus is arranged to effect automatic calibration and/or re-calibration of the sensor device when a difference between a value determined by the sensor device and a value determined by the analyser device in relation to the sample of bodily fluid is calculated in said comparison to be outside a target tolerance range. The arrangement may instead be such that the data from the sensor device and the data from the analyser device is displayed and the calibration and/or re-calibration can be effected manually.

The apparatus may comprise an analyser device arranged to withdraw samples at predetermined intervals. The apparatus may be arranged to withdraw samples at, for example, regular intervals.

The apparatus may be arranged such that the samples can be withdrawn through a sensor probe of the sensor device.

The sensor device and the analyser device may be suitable for determining any parameter suitable for providing information about patient condition. Preferably the sensor device can measure two or more parameters and the analyser device can measure at least two parameters that are also measured by the sensor device. Advantageously, the sensor device and the analyser device are each able to determine at least one parameter selected from pO_2, pCO_2, pH, Na^+, K^+, lactate, and glucose. Preferably the sensor device comprises at least sensing devices for determining pO_2, pCO_2 and pH. The sensor device may also include a temperature measuring device, for example, a thermocouple. Advantageously, the sensor device is suitable for insertion into, and the analyser device is suitable for analysing blood withdrawn from, a blood vessel.

The sensor device may be, for example, an optical sensor device of the type which detects changes in the spectroscopic characteristics of a sensor substance which is contained in the sensor device, typically in the sensor probe. In use, the substance is in contact with the bodily fluid (or is separated from it by a barrier which is permeable to the analyte to be sensed so that the analyte can diffuse from the fluid to the sensor substance) and reacts reversibly with the analyte in such a way that changes in concentration of the analyte in the bodily fluid cause corresponding changes

in the spectroscopic characteristics of the sensor substance. The changes may be, for example, changes in the absorption or in the fluorescence characteristics of the sensor substance.

The invention also provides a method of calibrating an invasive optical sensor device comprising monitoring substantially continuously a parameter relating to a bodily fluid of the patient using the sensor device, analysing a sample of that bodily fluid in an analyser device, comparing an analysis result obtained by the sensor device with an analysis result obtained by the analyser device, and effecting adjustment of data relating to the sensor device in dependence upon the comparison.

The adjustment may be effected automatically. The adjustment may be effected manually.

Preferably the history of the substantially continuous measurements is recorded, and the comparison is effected with the value of the substantially continuous measurement that obtained at the time of taking of the sample.

Preferably, samples of the bodily fluid are withdrawn and analysed at intervals. Advantageously, the samples are withdrawn and analysed at predetermined intervals. More advantageously, samples are withdrawn and analysed at regular intervals.

Preferably, at least one parameter selected from

pO_2, pCO_2, pH is measured by the sensor device and the analyser device.

The monitoring of blood gas concentrations can be of particular relevance in patients undergoing critical care, for example post-operatively or following trauma. In such patients, detection of a reduction in the oxygen concentration and/or an increase in the carbon dioxide concentration in bodily fluids can give early determination of the condition of the patient enabling appropriate treatment to be implemented promptly. Even where samples are taken frequently, the analysis of the samples ex vivo means that there is a delay between sampling and provision of the results, and the results merely provide a "snapshot" view of the patient's condition.

One illustrative embodiment of the invention will now be described in detail, with reference to the accompanying drawings in which:

Fig. 1 is a block diagram of an apparatus according to the invention; and

Fig. 2 is a flow diagram of a patient monitoring method using the apparatus of Fig. 1.

The apparatus comprises a sensor device having a sensor probe 1 which is suitable for insertion into a blood vessel of a patient to be monitored. For example, the sensor device may be a Paratrend (trade mark) continuous blood monitor manufactured by Diametrics

Medical Limited, which is suitable for monitoring oxygen (pO_2) and carbon dioxide (pCO_2) concentration and pH in blood. The sensor device is calibrated, for example, by placing the sensor probe 1 into a solution of known pO_2, pCO_2, and pH. The sensor further includes a sensor interface 2. The sensor probe 1 is connected via a sensor interface device 2 to a monitor 3, on which the measured values can be displayed in graphical or numerical form.

The apparatus also comprises an analyser device 4 for analysing samples of blood withdrawn from the patient. For example, an analyser device may be an IRMA (trade mark) device made by Diametrics Medical Inc. The IRMA is a blood analysis system in which a sample of blood can be withdrawn from the patient and placed in a cartridge which is arranged to be received in a sample space in a blood analyser where automatic analysis of the sample for various blood analytes can be carried out in vitro, including determination of pO_2, pCO_2, and pH. The analyser device 4 is connected via an analyser interface device 5 to a monitor 3, which in Fig. 1 is the same monitor as that to which the sensor interface device 2 is connected.

In the embodiment of Fig. 1 the sensor device, comprising probe 1 and sensor interface 2, and the analyser device 4 are in communication with each other via the monitor 3, which may contain a processor for

processing data received from the sensor device 1 and the analyser device 4. The apparatus comprises a sensor clock 6 in communication with the sensor device 1. The sensor clock 6 is shown in Fig. 1 as being associated with interface device 2 but may instead be integrated into the sensor probe 1 or monitor 3. The apparatus also has an analyser clock 7 in communication with the analyser device 4. The analyser clock 7 may be associated with interface device 5 as shown in Fig. 1, but may instead be integrated into the analyser device 4 or monitor 3.

In use, after calibration, the sensor probe 1 of the sensor device 1 is introduced into a blood vessel of the patient, for example, a radial or femoral artery.

The control device (the control device may be within one of, or distributed throughout, the sensor device 2, monitor 3 and analyser 4)enables synchronisation of the sensor clock 6 and the analyser clock 7. The sensor device comprising probe 1 and sensor interface device 2, commences substantially continuous collection of data relating to the analytes of interest in the blood and the data is passed via sensor interface unit 2 to monitor 3 where, after processing, it is displayed on the monitor 3. The control device registers readings from the sensor clock 6 and those readings are used to "time-stamp" the readings from the sensor device 1.

After substantially continuous monitoring for a

suitable interval, for example, 30 minutes to 8 hours, a sample of blood is withdrawn from the patient and immediately placed in the analyser device 4. The analyser clock 7 records the time of sample introduction as the sampling time. The analyser device 4 then proceeds to analyse the blood sample for various parameters, including at least one parameter that is being determined substantially continuously by the sensor device.

Following analysis of the sample by the analyser device 4, the measured values of the parameter or parameters and the sampling time are supplied to the control device. The control device scans the previously recorded data from the sensor probe 1 and sensor clock 6 and identifies, based on the sensor clock data, sensor readings which had been recorded substantially contemporaneously with the sampling time. The sensor readings are compared with the measured values from the analyser device for the same parameters. The comparison may be carried out by the control device and a report displayed on monitor 3 or, if preferred, the relevant data from the sensor device 1 and the analyser device 4 may be displayed separately for visual comparison by a clinician.

If the comparison shows that the analyser data varies from contemporaneous sensor data by more than a desired amount, for example, by more than 5% of the

value measured by the sensor, the sensor device automatically re-calibrates the sensor probe 1 based on the analyser values and data collection continues. If the difference from the analyser is smaller than the target value, data collection may continue without re-calibration.

The sampling and correlation steps are then repeated at appropriate intervals.

In practice, the measurement taken from a device such as the Paratrend device mentioned above will be affected only by a slow drift. Where such devices are used for relatively long periods in a patient, for example from 3 to 30 days, the cumulative drift over time may be material and conventional re-calibration cannot be carried out whilst the sensor probe is in place in the patient. An appropriate regime for correlation of the sensor device readings with analyser device readings will depend on the particular condition of the patient.

One form of regimen is set out in detail in Fig. 2, and includes the following steps:

Step I - Negotiation between sensor device and analyser device 4 to establish relative time.

Step IIa - Continuous data collection and data time-stamping by sensor device.

Step IIb - Time-stamping by analyser device 4 of sample taken from patient and evaluation of sample by

analyser device 4.

Step III - Results of sample analysis and sample time-stamp passed by analyser device 4 to sensor device 1.

Step IV - Processor instructed to effect correlation of data from analyser device 4 with data being collected continuously by sensor device.

Step Va - Correlation of data from sensor device 1 with data from analyser device 4.

Step Vb - Analyser device 4 awaiting acknowledgement from sensor device 1.

Step VI - Sensor device confirming successful correlation to analyser device 4.

The above steps can then be repeated at intervals as appropriate.

In one regimen sample withdrawal and analysis and correlation of the sensor device (if appropriate) based on analyser device readings may be carried out intermittently at regular intervals, for example, four-hourly or eight-hourly. In another suitable regimen sample withdrawal and analysis and correlation of the sensor device (if appropriate) may be carried out intermittently at the convenience of the clinician, for example, to coincide with routine ward visits.

In the arrangement described above, samples are withdrawn manually by an attendant and placed in the analyser device 4. If preferred, the analyser device

may be arranged automatically to withdraw samples and analyse them at predetermined intervals.

Further, it is also within the ambit of the invention for the time-stamped data from the sensor device and the time-stamped data from the analyser 4 to be displayed separately, for example on separate monitors, and for the clinician to determine whether re-calibration is appropriate and initiate appropriate adjustment of the sensor device.